

Peripheral Case Study

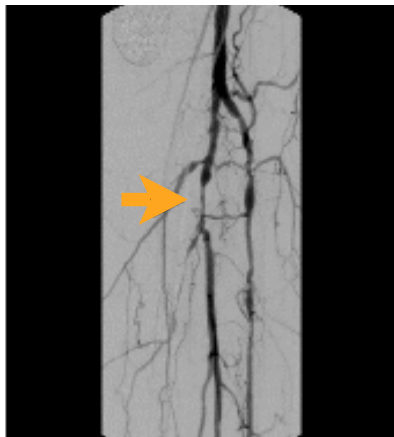
Courtesy of: Dierk Scheinert, MD
 Facility: Heart Center Leipzig, Germany

Patient History: This 75 year old female was classified as Rutherford Functional Class IV; her pre-procedure ABI was 0.4. Angiography revealed a moderately calcified 17 mm eccentric lesion in the mid tibio-peroneal trunk, with a minimal lumen diameter of 0.8 mm and a reference vessel diameter of 3.5 mm.

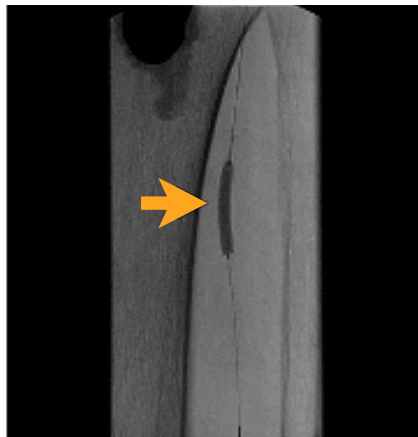
Tibio-Peroneal Disease

Procedure: A lesion with 80% stenosis was treated with a 3.5 x 20 mm AngioSculpt PTA catheter with one inflation to 8 atm resulting in no residual stenosis.

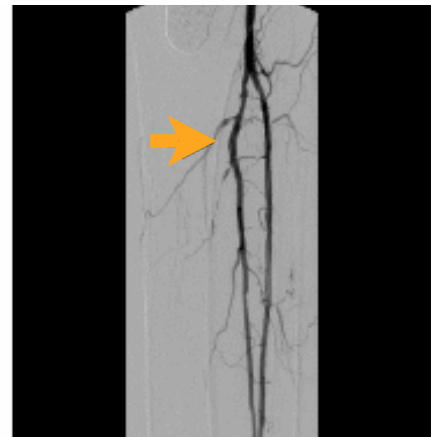
	Lesion Characteristics	
	Pre-AngioSculpt	Post-AngioSculpt
Minimal Lumen Diameter	0.8 mm	3.5 mm
Diameter Stenosis	80%	0%



Pre-AngioSculpt



AngioSculpt Deployment



Post-AngioSculpt

AngioScore, Inc. 5055 Brandin Court, Fremont CA 94538 www.angioscore.com
 Toll Free: 877-264-4692 Fax: 510-933-7901 email: info@angioscore.com

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.
 CE Mark Granted for Peripheral Applications.

SUMMARY OF SAFETY AND EFFECTIVENESS – PTA CATHETER

INDICATIONS

The AngioSculpt PTA Scoring Balloon Catheter is intended for dilatation of lesions in the iliac, femoral, ilio-femoral, popliteal, and infra popliteal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Not for use in the coronary or neuro-vasculature.

CONTRAINDICATIONS

None known for Percutaneous Transluminal Angioplasty (PTA) procedures.

WARNINGS

This device is intended for single (one) use only. Do not resterilize and/or reuse, as this can potentially result in compromised device performance and increased risk of inappropriate resterilization and cross contamination.

The inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis, in order to reduce potential vessel damage.

When the catheter is exposed to the vascular system, it should be manipulated while under high quality fluoroscopic observation.

Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.

Balloon pressure should not exceed the rated burst pressure (RBP). Refer to product label for device specific information. The RBP is based on results of in-vitro testing. At least 99.9% of the balloons (with a 95% confidence level) will not burst at or below their RBP. Use of a pressure monitoring device is recommended to prevent over-pressurization.

Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.

Proceed cautiously when using the AngioSculpt catheter in a freshly deployed bare metal or drug eluting stent. The AngioSculpt catheter has not been tested for post-dilation of stents or in lesions distal to freshly deployed stents in clinical studies. Bench testing has shown no additional risk when inserting or withdrawing the AngioSculpt catheter through stents (no interference with stent struts, no retention of or damage to the AngioSculpt catheter).

Use the catheter prior to the "Use Before" (expiration) date specified on the package.

PRECAUTIONS

A thorough understanding of the principles, clinical applications and risks associated with PTA is necessary before using this product. Any use for procedures other than those indicated in these instructions is not recommended. The device is not recommended for use in lesions which may require inflation pressures higher than those recommended for this catheter.

Do not use if package is opened or damaged.

Prior to angioplasty, the catheter should be examined to verify functionality, device integrity and to ensure that its size and length are suitable for the specific procedure for which it is to be used.

During and after the procedure, appropriate anti-coagulants, anti-platelet agents and vasodilators should be administered to the patient according to institutional practice for peripheral angioplasty of similar arteries.

Pass the AngioSculpt catheter through the minimum size guiding catheter or recommended introducer sheath size indicated on the product label.

POSSIBLE ADVERSE EFFECTS: Total occlusion of the treated artery, arterial dissection or perforation, arterial spasm, pseudo-aneurysm, restenosis of the dilated artery, embolism, thrombus, retained device components, hemorrhage or hematoma, arteriovenous fistula.